

TECHNIQUES

Required skills and interdisciplinary teams in starting a TEVAR practice

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The procedure of thoracic endovascular aortic repair (TEVAR) represents one of the most revolutionary advances in the history of modern vascular surgery. From its inception, there has been a demonstrated decrease in intraoperative blood loss, hospital length of stay, recovery period, morbidity (especially spinal cord ischemia and pulmonary complications), and early mortality over traditional open repair. Some patients, previously thought to be unfit for open thoracic aortic aneurysm repair, are now considered candidates for TEVAR due to the decreased intra- and postoperative complication rate. A recent Medicare population study showed a significant increase in endovascular procedures and a decrease in open surgeries to treat thoracic aortic disease.¹ TEVAR demonstrated a significant improvement in perioperative survival compared with open repair.

Since the US Food and Drug Administration (FDA) approval of the initial graft system in March of 2005,² TEVAR has rapidly gained acceptance among endovascular specialists. This adaptation has been accompanied by an explosion of a variety of endografts, as well as ancillary devices to complete the procedure safely. TEVAR may appear to be a more simplified procedure compared with infrarenal endovascular aneurysm repair (EVAR), but is, in reality, more complicated. Preprocedural imaging and planning, intraprocedural decision-making and technical considerations, as well as managing potentially life-threatening intraoperative complications all make TEVAR one of the most demanding endovascular procedures, alongside carotid artery stenting with distal protection.

Despite its highly technical requirements, TEVAR is one of the least frequently performed endovascular procedures, when one considers iliac, superficial femoral artery

(SFA), tibial, renal, carotid, and abdominal aortic aneurysm (AAA) procedures. At this time, vascular surgeons, cardiothoracic surgeons, and a few interventional radiologists and cardiologists are the specialists performing TEVAR procedures. The skill set required to care for these patients from preoperative to postoperative status may actually overlap several specialties, making collaboration essential in establishing a successful, productive TEVAR practice. In addition, no TEVAR practice can be successful without full and active support from the sponsoring institution, as well as industry. Devices and ancillary equipment, imaging systems, and support team personnel all represent significant capital investments and ongoing expenditures.

CREDENTIALING, EXPERTISE, AND SKILL SET REQUIREMENTS

TEVAR performance requires advanced endovascular skills, assuming one has already acquired a solid basic endovascular skill set. These basic skills include endovascular diagnostic and interventional procedures on all blood vessels except those intrinsic to the heart and brain, and the thoracic, vertebral, and internal carotid arteries, which require more advanced skills to manage. Currently, not all specialty training programs offer equivalent opportunities for basic endovascular training, although postgraduate training programs continue to expand their teaching, as more vascular specialists embrace endovascular procedures as viable treatment options for patients with vascular disease. Online surveys of vascular surgery fellows found that more than 80% of trainees received advanced endovascular training from vascular surgeons versus other specialists.³

Clinical privileges. Beyond the acquisition of basic endovascular skills, the question arises as to the actual guidelines for credentialing that should be met prior to performing TEVAR. Historically, various individual societies have attempted to establish credentialing guidelines and procedure volume requirements for hospital privileges for specific peripheral endovascular procedures.⁴ Oftentimes, these criteria were established to covertly protect the individual specialty, as well as create a standard environment for patient care and disseminate training expertise. Not until recently have two documents addressed the specific recommended credentialing requirements for TEVAR.

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The Society of Thoracic Surgeons/American Association for Thoracic Surgery (STS/AATS) Position Statement in 2006 recommended that a candidate participate in the management of 20 patients with thoracic aortic disease during the 2-year period prior to seeking privileges.⁵ The physician should have completed an Accreditation Council for Graduate Medical Education (ACGME)-accredited training program with management of thoracic aortic disease and have participated in at least 10 open thoracic aortic surgical procedures in the previous 2 years. The candidate should have performed at least 25 catheter/wire placements, participated in 10 EVARs or five TEVARs, and have experience with large-bore sheath placement and retroperitoneal iliac exposure. Participation in either an industry-sponsored or society-sponsored TEVAR course, such as the courses sponsored by the Midwestern Vascular Surgical Society, was suggested. It was recommended that physicians participate in continuing medical education (CME) programs, but the number of hours was not specified. Additionally, those who perform the procedure should document their results in a database format, so that outcome may be evaluated and potentially compared regionally or nationally.

The STS and AATS recognized that a single physician may not meet all the credentialing requirements and that partnering with another specialist or group was advisable. In this way, patients may benefit from a team approach with collaboration between different specialties. Even though cardiothoracic surgeons were encouraged to obtain the full skill set needed for TEVAR performance, they were urged to bring in shared expertise with a team of specialists.

The multispecialty consensus document from the Society for Vascular Surgery[®] (SVS), Society of Interventional Radiology (SIR), Society for Cardiovascular Angiography and Interventions (SCAI), and Society for Vascular Medicine and Biology (SVMB) in 2006 also recognized the importance of first obtaining a solid set of basic skills before embarking on setting up a TEVAR practice because performance of TEVAR requires an advanced knowledge base of thoracic aortic pathology, diagnosis, imaging, and management.⁶ Initially, few physicians possessed the entire set of knowledge and technical skills; therefore, collaboration between surgeons and interventionists is encouraged in order to form teams to provide comprehensive care to patients with thoracic aortic disease. As these procedures and adjuvant operations become more common, we will see individual practitioners seek full credentials. Until then, a multidisciplinary approach is recommended with full participation from all physician team members.

The Clinical Competence Statement from these societies included obtaining the highest level of certification available in the physician's specialty. They identified four knowledge and skill set requirements which could be gained individually or collectively. First, 25 EVARs or 10 TEVARs should be performed in the 2 years preceding TEVAR credentialing. These volumes are similar to FDA-approved device certification training requirements. Second, the achievement of standard endovascular credentials

according to either the American Heart Association training standards⁷ or the American College of Cardiology/American College of Physicians/SCAI/SVMB/SVS clinical competence statement.⁸ Cases and outcomes should be recorded in order to document under these guidelines. Third, all physicians or TEVAR teams should have acquired 10 hours of CME specifically pertaining to TEVAR in the previous 2 years before application and every 2 years thereafter to maintain accreditation. In addition, 10 TEVAR procedures performed over 2 years is the recommended minimum to maintain a credentialed program. Lastly, participation of a qualified surgeon in all TEVAR procedures is required in order to repair and maintain branch vessel (iliac and subclavian) integrity when it becomes necessary.

Credentialing differences. Although these two documents aim to create a similar endpoint by defining concrete training requirements for performing TEVAR, they differ in the absolute recommendations (Table). One of the more prominent differences is in the prior endovascular interventional experience. The SVS document requires 10 prior TEVAR and 25 EVAR procedures with demonstrated competency in peripheral interventions. The STS/AATS document specifies 5 TEVARs, 10 EVARs, and 25 prior catheter placements.

Learning curve analysis. It seems intuitive that with more experience, better outcomes can be achieved, and a recent learning curve analysis was completed to determine which level of experience is more appropriate for TEVAR.⁹ A previous learning curve analysis study for EVAR determined that as institutional experience increased, an individual surgeon's learning curve decreased.¹⁰ Much of the improvement in success was attributed to the first surgeon's clinical experience. In the TEVAR study, each of the three vascular surgeons had already acquired the more extensive endovascular background requirements of the SVS document but differed in their TEVAR volume. The target success rate was achieved with TEVAR prior case volume of 5 to 10, but it was unclear if these volumes would still be equivalent without the prior endovascular experience, which is not as stringent in the STS/AATS document.

The possession of significant previous endovascular experience prior to undertaking TEVAR is further supported by a Discussion and Study Group of the American Surgical Association.¹¹ They recognized that skills from more commonly performed surgical procedures often apply to less common surgeries and that the transference of these skills is appropriate when achieving an established volume requirement. Surgeons should define when these skill sets may be "transferable." When new procedures are introduced, credentialing requirements specific to the new procedure should be readily adopted, so that patients may benefit safely. It is assumed that surgeons should be able to provide medical care for surgical patients throughout the perioperative course with regards to the six core competencies: medical knowledge, practice-based learning, interpersonal and communication skills, professionalism, and technical skills. Maintenance of privileges for infrequently performed procedures should be linked to experience and

Table. Comparison between the SVS multispecialty clinical competence statement and the STS/AATS position statement

| Competency | SVS Multispecialty | STS/AATS |
|---|--|---|
| Residency training | Attain highest level of certification within specialty | Manage 20 patients with thoracic disease over previous 2 years OR complete ACGME-accredited CTS residency |
| Previous EVAR cases | 25 (or 10 TEVAR) | 10 (or 5 TEVAR) |
| Previous TEVAR cases | 10 (or 25 EVAR) | 5 (or 10 EVAR) |
| Previous open thoracic procedures | None required | 10 cases over 2 years |
| Previous endovascular experience | Have endovascular credentials as specified by ACC or AHA documents | 25 wire/catheter placements |
| Continuing Medical Education | 10 hours devoted to TEVAR over past 2 years | Recommended but not specified; participate in a society- or industry-sponsored TEVAR course |
| Thoracic aortic knowledge | Board certified in VS or TS OR 20 hours CME devoted to TEVAR | Manage 20 patients with thoracic disease over previous 2 years |
| Capability to treat access and branch vessels | Board certified in VS or TS | Experience with large-bore sheaths and retroperitoneal exposure |
| Maintenance of certification | 10 hours CME devoted to TEVAR every 2 years AND 10 TEVARs over 2 years | Not specified |
| Outcomes | Document cases and outcomes | Participate in established databases |

AATS, American Association for Thoracic Surgery; ACC, American College of Cardiology; AHA, American Heart Association; CME, Continuing Medical Education; EVAR, endovascular aneurysm repair; STS, Society of Thoracic Surgeons; SVS, Society for Vascular Surgery; TEVAR, thoracic endovascular aneurysm repair; TS, thoracic surgery; VS, vascular surgery.

satisfactory outcomes, including reoperations, readmissions, and death.

Hospital credentialing. In 2008, the SVS set forth recommendations for hospital privileges in vascular and endovascular surgery, which had not been revised since 2002.¹² Specifically, for recently trained fellows seeking to perform TEVAR, full basic endovascular privileges, completion of 25 EVARs (12 as primary operator), familiarity with management of aortic disease, and experience with adjunctive TEVAR surgical procedures are recommended. Full open thoracic aortic surgical privileges are not required. For already credentialed surgeons, 10 TEVARs in the last 2 years (the absolute number may be reduced if a robust EVAR practice is in place), 10 hours of TEVAR CME, and experience with adjunctive surgical procedures should be required for hospital credentialing. Again, open thoracic aortic privileges are not required. Registries with outcome data are highly recommended, and in fact, are required for maintenance of certification.

INTERDISCIPLINARY COLLABORATION

Professional competition is a natural occurrence in an environment where revenue and relative value units are scrutinized by practitioners and institutions. Unfortunately, competition between specialties may not always be in the best interest of our patients. Patients should be afforded the highest quality of care in an experienced program in order to achieve superior outcomes. They should be offered all appropriate treatment options, not just the one that may be offered by a single practitioner, trained only in that procedure. As recommended in the two consensus documents, this may be best accomplished through the establishment of a collaborative team, inclusive of two or even more specialties. Attention should be given

to the whole spectrum of care from patient selection to postoperative surveillance when considering team members. The value of a cardiovascular anesthesiologist should not be underestimated as an integral participant in a successful TEVAR program.

This collaboration may translate into the formation of a formal "Vascular Center," but this is not a necessity.¹³ Even less formal arrangements can benefit the entire program by increasing the referral base and subsequently, caseload. Opportunities to "cross-train" fellow physicians should be encouraged and welcomed, so that medical experience can be shared and optimized.

Fellowship programs should maintain a higher TEVAR volume in order to provide appropriate training for future vascular specialists who will render care to aortic disease patients.¹⁴ This may include the cross-training of fellows by a physician from a different specialty, as already exists in many programs. This can even be offered in a "trade" where training opportunities are exchanged between specialties in order to gain cross-knowledge. As vascular surgeons become more skilled interventionists, however, there has been a trend toward increased total number of cases performed by trainees, with the increase attributable to an increase in endovascular cases.¹⁵ The fellowship training program of the future may indeed be one in which a true vascular interventionist is produced, who provides only minimally invasive care.

Interdisciplinary collaboration and the adoption of TEVAR by more qualified physicians will be even more important in the future, based on workforce shortages and a shift in caseloads between specialists.¹⁶ Conservative estimates suggest a 19% shortage of vascular surgeons by 2050 by population analysis. As the population ages and the prevalence of vascular disease increases, the shortage will be

amplified. There has been a shift in who provides care as well, with vascular surgeons increasing inpatient market share from 27% to 43%, corresponding with a decrease in caseloads of interventional radiologists.¹⁷

HOSPITAL AND INDUSTRY SUPPORT

A successful TEVAR program is impossible without institutional support. Support can take multiple forms, including procedure training opportunities, personnel training, imaging systems, stock and equipment, marketing, and maintenance of a surveillance program. The hospital administration should be brought on board early when planning a new TEVAR program, so that efforts may be shared. When TEVAR volumes grow, growth in other programs, especially EVAR practices, should be anticipated.

Training. Training courses can be sought out from professional societies, industry, and other experienced practitioners. These can be expensive and take time away from an already busy practice. Training for operating room/interventional suite personnel and other ancillary services is equally important, as even a perfectly executed TEVAR requires expert care postoperatively to obtain superior clinical results. Physicians should take an active role in “on-the-job” training for operating room staff, as there may be few in the operating room who are able to assist with these technically challenging procedures. Even a straightforward TEVAR procedure requires expert intraoperative assistance, including circulating nurses, scrub techs, and radiology techs.

Imaging. Advanced imaging equipment may already exist at the institution, but if not, it is critical to have access to the best imaging available. An appropriate computed tomography scanner with three-dimensional capabilities is crucial to preoperative case planning and device choice. Intraoperatively, a portable C-arm may not provide adequate image quality, full rotational ability, or adequate field of view. Fixed fluoroscopic units offer better-quality images and a wider array of postprocessing options and storage capabilities (See the article by Dr Eagleton for a detailed intraoperative imaging discussion). Institutions should be encouraged to invest in appropriate imaging units, and physicians should participate in the decision-making process. A traditional operating room is not critical, since the conversion rate to an open, emergent procedure is rare.⁶ Sophisticated interventional suites with operative capabilities are in existence and preferred by some practitioners. The operating room environment, however, tends to be more comfortable to vascular and cardiothoracic surgeons and may provide a more convenient setting when a concomitant open procedure is necessary.

Stock and equipment. Since an active EVAR practice is pre-existent, most likely there is a wide variety of guidewires, catheters, and sheaths available. A main difference between the equipment needed for EVAR versus TEVAR is the length of devices and the need for stiff devices to pass through tortuous anatomy. Wires with lengths of 260 to 300 cm are necessary, and, depending on the location of

the proximal graft, wire tips are sometimes preshaped to adapt to the angle in the ascending aorta and aortic arch. If extreme aortic tortuosity exists and brachial access becomes necessary with a brachial-femoral wire technique, then even longer wires are a necessity. Typically, the wire that the graft is to be deployed over should have a stiff shaft, as endografts are stiff in configuration as well, and this provides better trackability and deliverability.

Catheters for accessing the thoracic aorta and arch branch vessels should be 90 to 100 cm in length. Diagnostic catheters with 1-cm spaced marker bands are helpful when determining aortic length to be covered. Catheters with various preshaped tips may be necessary when arch branch vessels have to be accessed. Intravascular ultrasound catheters are very useful when assessing landing zones and branch vessel locations, as well as determining true versus false lumen in dissection cases. Aortic occlusion balloon catheters should be readily available in the rare but devastating occurrence of aortic rupture.

Sheaths are meant to not only protect the femoral artery, but often the entire iliac system, from the traumatic passage of multiple large and irregular devices. Sheaths are sometimes built into the delivery system, but others require a separate sheath, up to 24 F outer diameter. Graduated dilators should be available in order to aid in the passage of these sheaths if necessary. Eight-to 10-mm-diameter Dacron or polytetrafluoroethylene grafts should most likely already be in stock, in the event that an iliac conduit becomes necessary to gain access. Covered stents or iliac endograft extensions should always be available in the event of iliac rupture, flow-limiting dissection, or stenosis requiring treatment beyond ballooning.

Other available equipment should include an array of shorter wires, catheters, and angioplasty balloons. These may be useful in the event of branch vessel complication and obtaining initial access. Large, unmounted balloon-expandable (Palmaz) stents may occasionally be needed to treat Type I leaks from an attachment site. Lastly, some physicians trained in the procedure may want to treat patients percutaneously and have Proglide or Prostar XL closure devices available. Khoynezhad et al have recently provided a review and description of multiple devices and their construction.¹⁸

Industry support is necessary when building an inventory of TEVAR endografts. These devices are very costly, and an agreement to consign them may be beneficial for the institution. Several devices should be investigated when deciding which to have on hand since one may be superior over others, depending on the clinical situation and a patient's anatomy. Having grafts in stock, however, may not be totally necessary unless intending to treat the emergency TEVAR patient. Industry clinical representatives are typically pleased to assist in case planning, ordering of grafts, and even providing “extra pieces” when necessary during a TEVAR procedure.

Marketing. Hospital administration should be willing to assist with marketing efforts for a new TEVAR program. Just as institutions with trauma programs tend to attract

more complicated cases for other specialties, a TEVAR program will generally attract other vascular referrals. A strong referral base will be built as excellent results are achieved and timely feedback back to referring physicians is provided.¹⁹ The various TEVAR team physicians should leverage their own referral system to increase visibility of the program. This is beneficial for all the specialties involved. Physicians should also work with billers and coders so that appropriate reimbursement is obtained for all parties (See the article by Dr Seabrook). This becomes especially important when several disciplines are involved. Establishing a true vascular center with a single cost center may be advantageous in some practices to minimize competition while maximizing collaboration and cost savings.

CONCLUSIONS

Launching a TEVAR practice differs from establishing other endovascular procedures. The disease process and patient population are vastly more complicated, the procedures are expensive and present a higher risk. The knowledge base required to care for the TEVAR patient from presentation to postoperative surveillance years later is not one commonly possessed by all vascular specialists, but is necessary to provide high-quality care to patients. Extensive basic endovascular skills are a necessity prior to embarking on a TEVAR program and comprehensive TEVAR training with the help of proctors, society-sponsored courses, and industry training initiatives are imperative.

A single physician may not possess all the skills and clinical knowledge base to care for the TEVAR patient, and the formation of teams with different specialists who collectively have all the expertise will become necessary. Hospital credentialing may be for an entire team, instead of a single physician. Hospital support for a new program is not only desirable but is a requirement to make a TEVAR practice successful. Institution administration and industry can assist in multiple areas to help a program thrive. All of these recommended skill sets, credentialing criteria, collaborative teams, and clinical support efforts are in the best interest of our patients.

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